K062365

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SEP 29 2006

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Arthrex Aspirate Kit

NAME OF SPONSOR:

Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

510(K) CONTACT:

Sally Foust, RAC
Regulatory Affairs Project Manager
Telephone: (239) 643-5553 ext. 1251
FAX: (239) 598-5539

TRADE NAME:

Arthrex Aspirate Kit

COMMON NAME:

Piston Syringe

DEVICE PRODUCT CODE/CLASSIFICATION:

FMF: Class II
21 CFR 880.5860

PREDICATE DEVICES

K041991: Aspirex™ Bone Marrow Aspirate Kit, IsoTis OrthoBiologics
K022246: Symphony Graft Delivery System, DePuy Acromed
K012738: Symphony Graft Delivery System, DePuy Acromed

DEVICE DESCRIPTION AND INTENDED USE

The Arthrex Aspirate Kit contains piston syringes, aspirating needle, Luer-lock and Slip Tip adaptors, cannula, and prep tray (bowl).

The piston syringes consist of aspirating/delivery syringe and/or a mixing/delivery syringe. The piston syringes are designed with male Luer-lock connectors (nozzle) for fitting a female connector of a needle or an adaptor for connection to the other syringe or cannula used for mixing. The aspirating syringe is a 60 mL syringe, while the mixing syringe is 9 mL. Luer-lock and Slip Tip adaptors may be provided.

The Arthrex Aspirate Kit is intended for the aspiration of bone marrow, autologous blood, plasma or other blood components with or without pre-filling with a bone void filler (allograft, autograft or synthetic bone graft material).

The kit is designed to facilitate the pre-mixing of autologous blood, bone marrow, I.V. fluids, platelet-rich plasma, or plasma with bone void filler and the delivery to

an orthopedic surgical site, as deemed necessary by the clinical use requirements.

SUBSTANTIALLY EQUIVALENCE

Arthrex has determined that the Arthrex Aspirate Kit is substantially equivalent to the predicate devices where basic features and intended uses are the same. Any design differences between the Arthrex Aspirate Kit when compared to predicate devices are considered minor and do not raise any questions concerning safety and effectiveness. Any differences have been found to have no apparent effect on the performance, function, or intended use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arthrex, Inc
% Sally Foust, RAC
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

SEP 29 2006

Re: K062365
Trade/Device Name: Arthrex Aspirate Kit
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: August 11, 2006,
Received: August, 14, 2006

Dear Ms. Foust:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

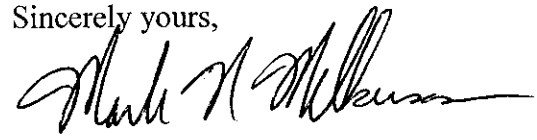
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, and Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062365

Device Name Arthrex Aspirate Kit

Indications for Use:

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The kit is designed to facilitate the pre-mixing of autologous blood, bone marrow, I.V. fluids, platelet-rich plasma, or plasma with bone void filler and the delivery to an orthopedic surgical site, as deemed necessary by the clinical use requirements.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062365